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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/980,614

04/17/2002

Yi Li

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EXAMINER

AZPURU, CARLOS A

ART UNIT

PAPER NUMBER

1615

MAIL DATE

DELIVERY MODE

04/10/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/980,614	Applicant(s) LI ET AL.	
	Examiner Carlos A. Azpuru	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 March 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15 and 16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15 and 16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of the amendment filed 03/31/2008.

The following is a new rejection of the claims:

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 15 and 16 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4, 5 and 9 of copending Application No. 11/027, 881 (US'881). Although the conflicting claims are not identical, they are not patentably distinct from each other because US'881 claims a

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method of transplanting stromal bone marrow cells to the CNS in order to treat various injuries (see claims 1 , 3 and 4). Administration may be intravenous or intrarterial (see claim 9). As such, those of ordinary skill would expect similar treatment of injury given the claims of copending US'881 given that the same cells are administered in the same way , to treat the same conditions. The instant claims would have been obvious to one of ordinary skill in the art at the time of invention given the claims of US'881.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Azizi et al.

Azizi et al disclose transplantation of human marrow stromal cells and astrocyte precursors (neurospheres) (see Abstract; page 3910, Results). The transplanted cells behaved like endogenous CNS stem cells (see Migration of Implanted Cells, page

3911). Finally, Azizi et al suggest the use of the transplant in the treatment of various disease. Azizi et al teaches the administration of the same cells, by the same route, to the same organ, and said cells migrate in the same way as claimed in the instant application. Azizi et al further provide the suggestion to use said implants in the treatment of various CNS diseases. While Azizi et al does indeed use a healthy brain, the mechanism of action of these migrated cells is an inherent property of these cells, not the condition of the brain. They would function in the same way regardless of the condition of the brain. Further, while applicant adds the term “penumbral”, this term merely refers to adjacent portions of the CNS as disclosed by Azizi et al. There is no specific “penumbral tissue” of the brain which differentiates the instant claims from the generic disclosure of Azizi et al to transplant these cells into CNS tissue, and for the same therapeutic purpose. Azizi et al does indeed show, survival, engraftment, and migration of these stromal cells. While Azizi et al also deliver their cells to a healthy CNS, there is no showing that delivery to damaged or diseased tissue would function any differently. Further, there is a clear suggestion to treat CNS diseases by Azizi et al. It is agreed that Azizi et al do not teach that the transplanted cells would differentiate into parenchymal cells in the brain. However, the evidence presented by the Azizi et al paper indicates that these transplanted cells do indeed become differentiated once they are transplanted given that they are said to behave like endogenous CNS cells. The process of differentiation of these cells is therefore expected once the cells are isolated, transplanted and migration takes place. Indeed, this migration appears to be evidence of differentiation. Further, while transplantation does not occur either intraarterially or

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intravenously, transplantation is accomplished. There does not appear to be anything unusual concerning these particular routes of transplantation which would materially change the migration or differentiation of the transplanted cells. Therefore, barring a showing that this transplantation would behave differently in healthy vs damaged central nervous tissue, and by these particular routes of transplantation, those of ordinary skill would have expected similar therapeutic results from the transplantation of cells as disclosed by Azizi et al. The instant claims would have been obvious to one of ordinary skill in the art at the time of invention given the disclosure of Azizi et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlos A. Azpuru whose telephone number is (571) 272-0588. The examiner can normally be reached on Tu-Fri, 6:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Carlos A. Azpuru/
Primary Examiner, Art Unit 1615

Carlos A. Azpuru
Primary Examiner
Art Unit 1615

caz